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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/647,919	08/26/2003	Paul Joseph Dominowski	PC25246A	2440

25533 7590 02/05/2010

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EXAMINER	
HILL, MYRON G	

ART UNIT	PAPER NUMBER
1648	

NOTIFICATION DATE	DELIVERY MODE
02/05/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

~IPGSKala@Pfizer.com

Office Action Summary	Application No.	Applicant(s)	
	10/647,919	DOMINOWSKI, PAUL JOSEPH	
	Examiner	Art Unit	
	MYRON G. HILL	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 November 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-23,25 and 28-75* is/are pending in the application.

4a) Of the above claim(s) *12-19 and 32-75* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-23, 25 and 28-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/26/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Please note the examiner of this application has changed.

The action is in response to the papers filed 11/5/09 and 11/6/09.

Claims 20-23, 25 and 28-31 are under examination.

Petition under Rule 48 to Correct Inventorship

In view of the papers filed 2/5/08 and 11/6/09, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(a). The inventorship of this application has been changed by adding Mark D. Goodyear and Michael J. Huether. Thus, the inventors are now Paul Dominowski, Mark D. Goodyear and Michael J. Huether.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected.

Information Disclosure Statement

A signed and initialed copy of the IDS paper filed 10/26/09 is enclosed.

Rejection Maintained

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 20-23, 25 and 28-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bowland et al. and Fulton et al. in view of Lidgate et al. (Pharmaceutical Research, 1989, Vol. 6, No. 9, pages 748-752) and Brake et al. (US PAT 6787146).

Applicant argues that there are four points to support an obviousness rejection in MPEP 2141 and argue that just because references can be combined does not render the invention obvious and the prior art must teach the desirability of the combination.

Also, applicant argues that the references are defective for not teaching several elements.

Also, that Lidgate does not test vaccines to be immunoprotective but only immunogenic. And cites In re Wright concerning vaccines inducing an immunoprotective response.

Also, that the examiner has used hindsight and it would be proper to withdraw the invention.

Applicant's arguments have been fully considered and not found persuasive.

The claims are drawn to a composition that comprises various elements (viral and bacterial antigens/virus) and the preamble refers to vaccine and microfluidized. The claims are drawn to a product. It is noted that Boland is a review of various combination vaccines on the market and Fulton et al. also teach combination vaccines.

Upon review of the Boland reference, it appears to teach more than noted by the previous examiner and asserted by applicant. Boland notes that (page 36, table 1 continued, footnote at top of page) BVDV is known known in two serotypes and biotypes and that they are independent of each other. Boland teach that several different adjuvants are used in vaccines (Table I).

From the Table 2 in Fulton, it is clear that vaccines comprising BVDV types 1 and 2 give the best response (seeTable 2, compare vaccine 3 to vaccines 1, 2, or 4).

One of ordinary skill in the art at the time of invention would have been motivated to make vaccines with both BVDV types I and II because Fulton clearly shows that vaccines with both give broader protection.

Barr, previously made of record, teaches ISCOMS which are adjuvant formulations made with saponin and oil-water. Additionally, Brake discloses veterinary acceptable adjuvants comprising SEAM62 (column 8, lines 36-50) which comprises an oil-in-water emulsion containing Quil A, lecithin and cholesterol (column 12, lines 59-67).

One of ordinary skill in the art would have been able to choose between the veterinary acceptable vaccine adjuvants known.

Applicant's arguments concerning *In re Wright* are not persuasive because the materials used to make the composition start off as vaccines. One of ordinary skill in the art would not formulate a vaccine composition to be no longer a vaccine when the intention is vaccine. Also, the fact pattern in *In re Wright* has to do with an enablement rejection not prior art. The case does discuss the difference between immunogenic and protective immune response. Those terms are not at issue here.

As far as the "microfluidized" is concerned, Lidgate (previously discussed) does teach advantages of microfluidized formulations.

It is not clear from applicant's argument what is not obvious about the combination in the rejection. The desirability of the combination is obvious in light of the teachings of Bowland that indicate that many combination vaccines are known and that it is desirable to vaccinate againrst the most common bovine diseases.

Thus, the rejection is maintained.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MYRON G. HILL whose telephone number is (571)272-0901. The examiner can normally be reached on M-Th and flex.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. G. H./
Examiner, Art Unit 1648

/Mary E Mosher/
Primary Examiner, Art Unit 1648